K11110

JUL 22 2011

510(k) Summary

12-Jul-11

Company	Advanced Brain Monitoring, Inc. 2237 Faraday Avenue, Suite 100 Carlsbad, CA 92008 Tel – (760) 720-0099 Fax – (760) 476-3620
Official Contact:	Daniel J. Levendowski
Proprietary or Trade Name:	Apnea Guard
Common/Usual Name:	Device, anti-snoring Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea
Classification / CFR:	LRK - CFR 872.5570
Device:	Apnea Guard
Predicate Devices:	K062951 – Airway Management – TAP III

Device Description:
The Apnea Guard is a Mandibular Repositioning Device (MRD) which consists of interlocking upper and lower trays filled with silicone retention material fitted to the patient. The useful life of the retention material will limit the Apnea Guard's used to a temporary appliance, less than 30 days. The trays are locked into a position that advances the mandible for the treatment of snoring and / or obstructive sleep apnea. The one-size-fits-all appliance is able to accommodate the full range of dental etiologies, including wide and narrow arches, missing or compromised teeth and gums, etc.

Indications for Use:
The Apnea Guard is a mandibular repositioning device intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in patients 18 years and older. The Apnea Guard is intended to be fitted with assistance from a healthcare professional, and used during sleep for less than 30-nights.

Patient Population:
Patients 18 years or older who snore or have mild to moderate obstructive sleep apnea (OSA)

Environment of Use:
Home, dental and physician offices, sleep laboratories as well as hospitalized patients where the Apnea Guard may be appropriate.

Contraindications:
Missing. Loose, infected teeth, Temporary crowns or fillings, TMJ

Comparison of Proposed Device vs. Predicate

	Apnea Guard	Airway Management TAP III - K062951
	Attributes	
Indications for Use	The Apnea Guard is a mandibular repositioning device intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in patients 18 years and older. The Apnea Guard is intended to be fitted with assistance from a healthcare professional, and used during sleep for less than 30-nights.	To reduce or alleviate night time snoring and mild to moderate obstructive sleep apnea (OSA)
Environments of use	Home, dental and physician offices, sleep laboratories as well as hospitalized patients where the Apnea Guard may be appropriate.	Home, Dental offices, Sleep laboratories
Patient Population	Patients 18 years and older	Adult patients 18 years and older
Contraindications	• Missing, infected, loose teeth • Temporary crowns or fillings • Temporomadibular Joint (TMJ) dysfunction	• Missing, infected, loose teeth • Temporary crowns or fillings • Temporomadibular Joint (TMJ) dysfunction
Prescription	Prescription use	Prescription use
Single patient, multi-use	Yes	Yes
Limitation of duration of use	< 30 days	No limitation
	Design	
Upper and lower trays fitted to the patient	Yes	Yes
Tray filled with impression material	Yes	Yes
Adjustment method for setting the amount of protrusion	Yes Manual and then held in place with a clip	Yes Screw mechanism
Works by holding lower jaw forward	Yes	Yes
Cleaned by simple rinsing with water	Yes	Yes
	Performance	
Materials used	Silicone impression material	Acrylic for trays Dental grade impression material
Biocompatibility	Testing according to ISO 10993-1	
Sleep study performance **Reduced AHI**	Statistically significant reduction in overall and supine position found to be equivalent to custom appliance, 56% and 63% showed > 50% reduction in overall and supine AHI, respectively.	72%
Bench Testing	Environmental, Mechanical, Device specific performance tests	

Discussion of Substantial Equivalence
The Apnea Guard is viewed as substantially equivalent to the predicate device because:

Indications –
Substantially equivalent to predicate – K062951 – Airway Management TAP III – Indicated to reduce or alleviate night time snoring and treat mild to moderate obstructive sleep apnea (OSA).

Technology –
Substantially equivalent to predicate – K062951 – Airway Management TAP III – both devices use a separate tray design with a means to adjust the lower jaw. Each is filed with an impression material to assure a tight fit for the user.

Materials –
The materials in contact with the patient have been tested per ISO 10993.

Environment of Use –
Substantially equivalent to predicate – K062951 – Airway Management TAP III – except we have added the use in hospitals and sub-acute care settings which are all under supervised care and observation.

Patient Population –
Identical to predicate –Airway Management TAP III – 18 years and older

Performance Testing
Bench testing included:

- Design performance was evaluated looking at tray design, strength, compression, extension and collapse and Locking mechanism
- Impression Material Retention
- Storage temperature at elevated and low temperatures
- User fit and comfort evaluation

Clinical testing included:
A sleep study comparing the proposed vs. predicate device was performed. This study included eighteen patients who underwent a prospective IRB approved study. Patients were studied to assess outcomes when compared with the predicate device. Patients successfully complete a two-night Qualification Home Sleep Test (HST). Measurement and recording of Apnea Index, Apnea-Hypopnea Index, Hypoxemia, Snoring, and Sympathetic Arousals was done and compared to the predicate.

Conclusions of Performance Testing

The bench demonstrated that the Apnea Guard design and performance meets is design requirements and was found to be equivalent in performance to the predicate for the intended use.

The clinical study with the Apnea Guard demonstrated that it was equivalent to the predicate in reducing sleep disordered breathing, hypoxemia, snoring, and sympathetic arousals in patients with mild to moderate OSA

The Apnea Guard was found to be substantially equivalent and does not raise any new safety or efficacy issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Advanced Brain Monitoring, Incorporated
C/O Mr. Paul Dryden
President, Regulatory Consultant
Promedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134

JUL 22 2011

Re: K111110
Trade/Device Name: Apnea Guard
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices For Snoring And Intraoral Devices For Snoring And Obstructive Sleep Apnea
Regulatory Class: II
Product Code: LRK
Dated: June 28, 2011
Received: June 29, 2011

Dear Mr. Dryden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CD RH/CDRHOffices/ucm1 15809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K111110

Device Name: Apnea Guard

Indications for Use:

The Apnea Guard is a mandibular repositioning device intended to reduce or alleviate snoring and mild to moderate obstructive sleep apnea (OSA) in patients 18 years and older. The Apnea Guard is intended to be fitted with assistance from a healthcare professional, and used during sleep for less than 30 nights.

Environment of Use:
Home, Dental and Physician offices, Sleep laboratories as well as hospitalized patients where the Apnea Guard may be appropriate.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111110